



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Sedanine® Oral Gel

Version number: 1.0

Date of compilation: 05.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	Sedanine® Oral Gel
Active substance	Acepromazine 35 mg/ml
Registration number (REACH)	Not relevant (mixture)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Veterinary medicinal product Consumer uses Professional uses
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1.3 Details of the supplier of the safety data sheet

Floris Veterinaire Produkten BV
Kempenlandstraat 33 / 35
5262 GK Vught
Netherlands

Telephone: +31 (0)73 656 76 47
e-mail: info@florispharma.com
Website: www.florispharma.com

e-mail (competent person) info@florispharma.com

1.4 Emergency telephone number

Emergency information service This number is only available during the following office hours: Mon-Fri 09:00 - 17:00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Medicinal products for human or veterinary use, as defined in Directive 2001/83/EC and Directive 2001/82/EC in their final state and intended for the final user are exempted for both classification and labeling according to EU Directive 1999/45/EC art. 1.5 and Regulation EC 1272/2008 art. 1.5.

Additional information

According to Regulation EU 1272/2008; Article 1.5:

This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

- (a) medicinal products as defined in Directive 2001/83/EC;
- (b) veterinary medicinal products as defined in Directive 2001/82/EC;
- (c) cosmetic products as defined in Directive 76/768/EEC;
- (d) medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;
- (e) food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used:
 - (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
 - (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;
 - (iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;
 - (iv) in animal nutrition within the scope of Directive 82/471/EEC.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Document is outside the scope of Regulation (EC) No. 1272/2008 (CLP).

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.



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SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

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Active substance: Acepromazine 35 mg/ml.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

Following skin contact

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth with water (only if the person is conscious). Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO₂);
Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

Water jet.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

During fire hazardous fumes/smoke could be produced.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133). Standard protective clothing for firefighters.



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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- flammability hazards

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

- incompatible substances or mixtures

Keep away from alkalis, oxidising substances, acids.

Control of effects

Protect against external exposure, such as

UV-radiation/sunlight. High temperatures, cold, frost.

Consideration of other advice

Keep container tightly closed.

- specific designs for storage rooms or vessels

- storage temperature

Minimum storage temperature: 15 °C
Maximum storage temperature: 25 °C

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- packaging compatibilities
- Keep only in original container.

7.3 Specific end use(s)

There is no additional information.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

No information available.

Relevant DNELs/DMELs/PNECs and other threshold levels

No data available.

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection (EN 166).

Skin protection



Protective clothing (EN 340 & EN ISO 13688).

- hand protection



Wear suitable gloves. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Chemical protection gloves are suitable, which are tested according to EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- breakthrough times of the glove material

Use gloves with a minimum breakthrough times of the glove material: >10 minutes (permeation: level 1).

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling. Provide eyewash stations and safety showers at the workplace.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Full face mask/half mask/quarter mask (EN 136/140).

Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. Keep away from drains, surface and ground water.



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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid (gel)
Colour	clear, yellow
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Evaporation rate	not determined
Flammability	non-combustible
Lower and upper explosion limit	LEL: UEL: not relevant
Flash point	not applicable
Auto-ignition temperature	not relevant
Decomposition temperature	no data available
pH (value)	not determined
Kinematic viscosity	not determined

Solubility(ies)

Water solubility	not determined
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Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	not determined
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Density	not determined
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Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
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Other safety characteristics

Miscibility	Completely miscible with water.
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SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Oxidisers.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

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Acute toxicity

Shall not be classified as acutely toxic.

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).



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Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Biodegradation

The relevant substances of the mixture are readily biodegradable.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Information on this property is not available.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

not subject to transport regulations

14.2 UN proper shipping name

not relevant

14.3 Transport hazard class(es)

none

14.4 Packing group

not assigned

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

There is no additional information.



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14.7 Maritime transport in bulk according to IMO instruments

No data available.

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - additional information

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant provisions of the European Union (EU)

Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LEL	Lower explosion limit (LEL)
PBT	Persistent, Bioaccumulative and Toxic



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Abbr.	Descriptions of used abbreviations
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
UEL	Upper explosion limit (UEL)
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product. For this product it is not legally required to provide an SDS under Article 31 of the REACH Regulation, because the product is not classified as hazardous. This document is prepared as a voluntary and additional service to provide general safety information.